-FINAL COPY-5/17/2018

Kentucky Colon Cancer Screening Program Annual Report July 2014 to June 2016

This report was prepared by

The Kentucky Department for Public Health

Division of Prevention and Quality Improvement

Chronic Disease Prevention Branch

in Collaboration with

The Kentucky Colon Cancer Screening Advisory Committee

The Kentucky Colon Cancer Screening Advisory Committee

John M. Bennett, MD, MPH, Chair Primary Care, Veterans Administration

Whitney Jones, MD, Co-Chair Midwest Gastroenterology Associates, Colon Cancer Prevention Project

Katie Bathje

Director, Kentucky Cancer Consortium

CJ Jones Kentucky Department of Medicaid Services

Connie Sorrell

Director, UL Kentucky Cancer Program

William F. Beam Colon Cancer Survivor

Janikaa Sherrod

Kentucky African Americans Against Cancer

Shawn Crabtree

Director, Lake Cumberland District Health

Dept.

Debra Armstrong, MSW, MPA

Director, UK Kentucky Cancer Program

Mark Evers, MD

Director, UK Markey Cancer Center

Donald M. Miller, MD, PhD

Director, UL Brown Cancer Center

Benjamin Lee Kessinger III Kinkead & Stilz, PLLC

Amanda Smart

Director, Colon Cancer Prevention Project

Erica Palmer Smith

American Cancer Society Cancer Action

Network

Connie Gayle White, MD, MS, FACOG

Deputy Commissioner for Clinical Affairs

Kentucky Department for Public Health

Eric Durbin, DrPH, MS

Director, Kentucky Cancer Registry

Tom Collins

University of Kentucky Rural Cancer

Prevention Center

Jack Hillard

Director, Kentucky Cancer Foundation

Rep. Melinda Gibbons Prunty

Speaker of the House appointee

Sen. Alice Forgy Kerr

President of the Senate appointee

Kentucky Department for Public Health Staff

Brian Boisseau, BA, Cancer Program Manager Sue Thomas-Cox, RN, CMAC, Chronic Disease Prevention Branch Manager

Janet C. Luttrell, Kentucky Colon Cancer Screening Program Manager

Becki Thompson, BSN, Kentucky Colon Cancer Screening Program Clinical Support Teri Wood, PhD, Epidemiologist, Chronic Disease Prevention Branch

Table of Contents

Table of Contents

The Kentucky Colon Cancer Screening Advisory Committee	2
Message from the Kentucky Colon Cancer Screening Advisory Committee	4
Executive Summary	5
Implementation	6
KCCSP Service Guidelines	6
Selection of Colon Cancer Screening Sites	6
KCCSP Funded Sites FY 15/16	7
Colon Cancer Screening Education and Outreach	8
Program Outcomes July 2013 to June 2016	8
KCCSP Fecal Immunochemical Test Outcomes	8
KCCSP Colonoscopy Outcomes	9
KCCSP Service Quality Outcomes	11
Review of Colorectal Cancer Cases – Demographics, Pathology, Staging and Surv Status	
Recommendations	
Background – changes to eligibility and covered services	
Further Recommendations	
Appendix A: Statutes and Administrative Regulations	16

Suggested Citation: Kentucky Colon Cancer Screening Program Annual Report 2014-2016, Kentucky Department for Public Health, Chronic Disease Prevention Branch

Please direct requests for additional information to:

Brian Boisseau, Health Program Administrator Kentucky Colon Cancer Screening Program Chronic Disease Prevention Branch Division of Prevention and Quality Improvement Kentucky Department for Public Health 275 East Main St., HS2W-E Frankfort, KY 40621

Email: Brian.Boisseau@ky.gov

Message from the Kentucky Colon Cancer Screening Advisory Committee

Colon cancer is a significant health problem in Kentucky - it is the second leading cause of cancer death when rates for men and women are combined. Despite successes over the years in raising screening rates, many Kentuckians are not screened for colon cancer according to the American Cancer Society (ACS) guidelines. Most colon cancers can be prevented by removing polyps before they develop into cancer.

According to the Kentucky Revised Statutes 214.540-544, the Kentucky Colon Cancer Screening Program and the Kentucky Colon Cancer Screening Advisory Committee were established for three purposes:

- 1) Increasing colon cancer screening;
- 2) Reducing morbidity and mortality from colon cancer; and
- 3) Reducing the cost of treating colon cancer among citizens of the Commonwealth.

As part of KRS 214.544, the Kentucky Colon Cancer Screening Advisory Committee (KCCSAC) provides recommendations for the overall implementation and conduct of the screening program and completes reports on implementation and outcomes and recommendations for the program annually. This report encompasses the final two years of the program for which funding was available, July 2014 through June 2016.

Efforts to advance the three purposes of the screening program are incremental and can only be accomplished in partnership with others.

John M. Bennett, MD, MPH

Chair, Kentucky Colon Cancer Screening Advisory Committee

Executive Summary

Implementation

The Kentucky Colon Cancer Screening Program (KCCSP) first received state general funds and Kentucky Cancer Foundation funds to offer services in fiscal year 2013. Working with the Kentucky Colon Cancer Screening Advisory Committee (KCCSAC), the Kentucky Department for Public Health (KDPH) developed guidelines and protocols for the KCCSP operations to ensure effectiveness and consistency across all funded sites. Partnerships in communities between local health departments (LHDs), providers, hospitals, and the Kentucky Cancer Program were essential to the success.

Program Outcomes

Through the program, a total of 1,128 fecal immunochemical test (FIT) screenings were conducted between January 2013 and June 2016. Fiscal Year 2014 saw the largest number of people screened by FIT at 453. This was the first full year of program operation, and prior to passage of the Affordable Care Act (ACA) and Medicaid expansion which increased individuals' access to insurance. In the final year in which the program received funding, 167 people were screened by FIT. Between January 2013 and June 2016, seventy-seven (6.8%) of the 1,128 people screened with FITs had positive results and were referred for a colonoscopy.

Eight hundred thirty people received screening or diagnostic colonoscopies between January 2013 and June 2016. Just as with FIT screenings, the highest number of services were provided in fiscal year 2014, with 443 people receiving a colonoscopy. In the final year in which the program received funding, 88 people received a colonoscopy. Two hundred thirty-four of all colonoscopies (28%) resulted in the patient having an adenomatous polyp removed.

Colon Cancers Detected

One cancer was diagnosed in the first 6 months of program operation (January 2013 to June 2014); eight colorectal cancers were diagnosed in the second year between July 2013 and June 2014, and four more colorectal cancers diagnosed in the third year of operation between July 2014 and June 2015. There were no colorectal cancers diagnosed during the final year of program operation spanning July 2015 to June 2016.

A follow-up query of those diagnosed with cancer was run in October 2017 through the Kentucky Cancer Registry. Of the 13 people diagnosed with cancer in the program, 10 of them no longer showed evidence of cancer and two are living with cancer. One person who is deceased, died from a cause not related to their cancer.

Implementation

KCCSP Service Guidelines

At the center of these guidelines are evidence-based criteria for determining who is eligible for colorectal cancer (CRC) screening and the best test to use for that individual. To be eligible for this program, clients must be between the ages of 50-64 (or age 45-64 for African Americans) or qualify with certain high risk conditions/factors; be a United States citizen or qualified alien; be a legal resident of Kentucky and uninsured; and their income must be at or below 250% of the federal poverty level.

Eligible clients determined to be at average risk for colon cancer are screened using a take home test called a FIT (Fecal Immunochemical Test), which uses antibodies directed against human hemoglobin to detect blood in the stool. The person uses the FIT kit to collect a small stool sample, which is mailed to the screening site for analysis. The use of FITs is very cost effective in comparison to the much higher expense associated with colonoscopy. When done on an annual basis, FIT screening is highly accurate in detecting adenomas in the lower colon.

A colonoscopy is the screening test of choice for clients who are found to be at moderate or high risk for colon cancer and those who have a positive FIT result. These clients are connected with a health care provider contracted by the program to receive a colonoscopy to identify and remove any benign, precancerous, or cancerous polyps. Removal of polyps before they become cancer saves lives and reduces health care costs by avoiding expensive surgeries or treatment of advanced cancer with chemotherapy or radiation.

One key component of the program is the use of patient navigators to assist the patient in successfully completing the colon cancer screening process. Each funded site is required to identify patient navigators who then complete a training program conducted by state KCCSP staff. The patient navigator guides the client through each step of the colon cancer screening process and documents the test results in the state laboratory data system.

The funded LHD sites are required to establish contracts with local health care providers who are contractually responsible for any needed pre-colonoscopy medical clearance and for all services connected to the colonoscopy, including preparation for the procedure, facilities charges, anesthesia, and removal of any polyps with pathology.

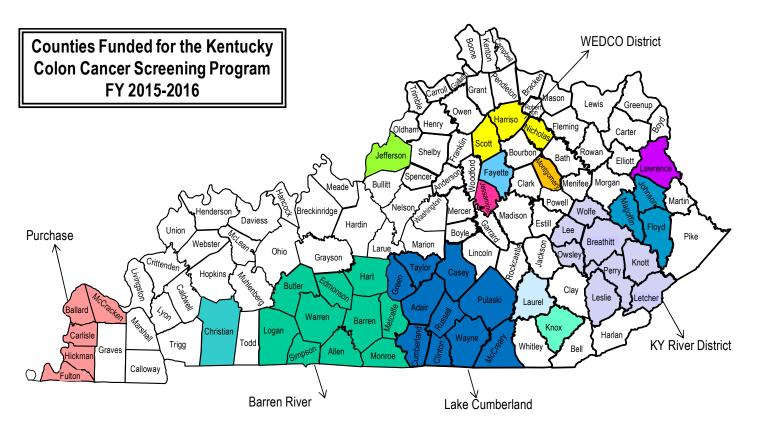
Selection of Colon Cancer Screening Sites

Working with the KCCSAC, staff at KDPH developed a request for application (RFA) process to solicit applications from LHDs and their partners. LHDs brought together community partners to apply for this funding, while serving as the fiscal agent in administering these funds. As fiscal agent, the LHD receives the grant funds from the KDPH and establishes contracts with local hospitals, endoscopists, federally qualified health centers (FQHC)s, community health clinics, or other providers as necessary to carry out services funded under this grant. Service providers must document services related to the CRC screening, as well as screening results, and supply this written information to the LHD for reimbursement at the specified rates.

The grant applications were reviewed by members of the KCCSAC and state KCCSP staff, which scored the proposals on a number of criteria. Applicants were awarded funding based on their applications with only minor adjustments to align with the program requirements. The average grant award was \$50,000 - \$75,000 per applicant per year.

KCCSP Funded Sites FY 15/16

14 Funded CRC Screening Sites



Colon Cancer Screening Education and Outreach

KRS 214.544 directs the Cabinet for Health and Family Services (CHFS) to contract with the Kentucky Cancer Program (KCP) at the University of Kentucky and the University of Louisville to work within its network of regional cancer control specialists, 15 district cancer councils and community partners across the state to establish a colon cancer screening education and outreach program in each of Kentucky's Area Development Districts.

KCP collaborated with LHD staff at each of the 14 funded health departments to provide professional and public education to promote KCCSP services and facilitate referral for colon cancer screening. KCP regional cancer control specialists participated in local KCCSP planning meetings, teleconference calls, and assisted in planning and participating in statewide forums.

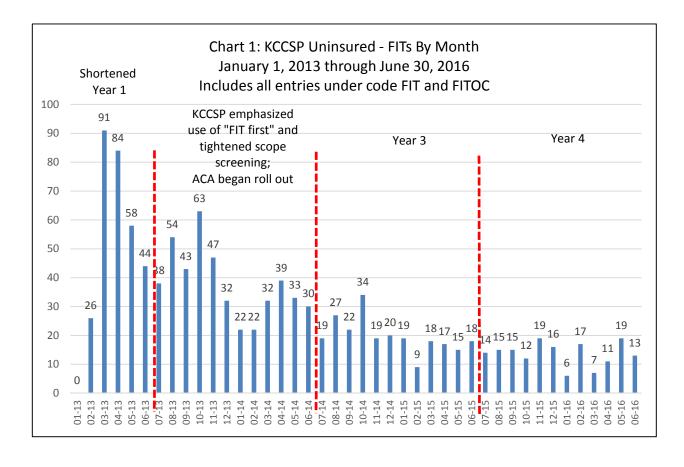
KCP collaborated with the KCCSP, the Kentucky Cancer Consortium, and the Colon Cancer Prevention Project to develop a campaign to educate providers and organizations about the services of the KCCSP program and the benefits of using FIT as part of a blended strategy for colon cancer screening. The campaign included 826 educational visits with organizations and health care providers by KCP regional cancer control specialists. Online continuing medical education was provided to 95 health care providers, and 1,594 patient brochures, fact sheets and posters were provided. KCP coordinated 60 public education events where a total of 65,380 people toured an inflatable colon.

Program Outcomes July 2013 to June 2016

KCCSP Fecal Immunochemical Test Outcomes

June 2016 was effectively the end of active services in the KCCSP. In order to give a comprehensive overview of services and outcomes for the program, data for the entire time period services were provided has been included. The data is presented by fiscal year to illustrate the flow of services from inception to the end of the funding period. Table 1 below shows the number of FIT screenings returned each fiscal year, and the number and percent of positive tests for fecal occult blood. It is important to note that rollout of the Affordable Care Act occurred during fiscal year 2014, resulting in a shrinking of the pool of uninsured age and income appropriate people in the target population. The impact of that decrease is evident in the decline in the number of services as illustrated in Chart 1 below, showing FIT services by month. Communication with patient navigators in the field confirmed that it became more difficult to find eligible participants. In fact, the navigators frequently connected uninsured individuals to the health insurance exchanges where they were able to sign up for insurance that would cover colorectal cancer screening.

Table 1: Fecal Immunochemical Test (FIT) Results by Fiscal Year (Source: KCCSP database)				
Fiscal Year	# FITS Resulted	# Negative	# Positive	
January - June 2013	270	250 (92.6%)	20 (7.4%)	
July 2013 - June 2014	453	426 (94.0%)	28 (6.2%)	
July 2014 - June 2015	238	227 (95.4%)	12 (5.0%)	
July 2015 - June 2016	167	148 (88.6%)	19 (11.4%)	
Grand Total	1128	1051	77 (6.8%)	



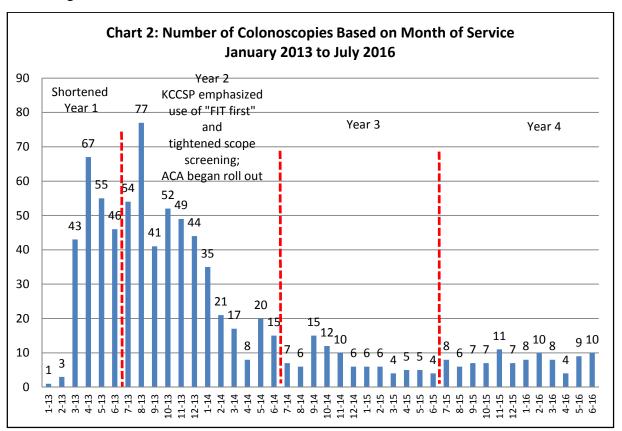
KCCSP Colonoscopy Outcomes

Table 2 below shows the number of colonoscopies done each fiscal year, and the general pathology of any polyps removed during the procedures or diagnoses of colorectal

cancers. The adenoma detection rate (ADR) for the program was 28%, slightly above the accepted ADR quality standard of 25%. Anything below the quality standard would have given the KCCSP reason for further review.

Table 2: Colonoscopy Results by Fiscal Year (Source – KCCSP database)						
Fiscal Year	# of Colonoscopies	Cancer	High Grade Adenoma	Non-High Grade Adenoma	Hyperplastic Polyp	Negative
Jan 2013/ June 2013	215	1	6	56	31	120
July 2013 / June 2014	433	8	2	106	74	242
July 2014 / June 2015	94	4	2	27	12	50
July 2015 / June 2016	88	0	4	31	13	38
Grand Total	830	13 (2%)	14 (2%)	220 (26%)	130 (16%)	450 (54%)

Chart 2 below shows the number of colonoscopies done by month for the duration of the program. Similar to the FIT chart above, the drop off in the number of monthly services coinciding with the roll out of the ACA is clear.



KCCSP Service Quality Outcomes

It is very important to assure patients in this program receive high quality and convenient services. FITs come in 1-sample, 2-sample, and 3-sample options. For simplicity of use and compliance in getting returned tests, the program chose to use 1-sample FIT kits with the highest sensitivity available in its sites, and developed a training program for patient navigators to ensure that they were well versed in teaching patients how to collect the sample and return the test. High quality colonoscopy preparation is vital for successful visualization of the colon mucosa to find and remove polyps. Patient navigators were educated in different types of colon prep products and routines, and reinforced instructions given to patients by the colonoscopy provider at each site. The adenoma detection rate of 28% reported in Table 2 is one measure of the success of patient navigators in assuring patients understood how to conduct the pre-colonoscopy preparation and in the skill level of the contracted providers.

KCCSP staff conducted site visits to assess effectiveness of the working partnerships, reinforce the information shared in the patient navigator trainings, and to confirm that each grant site was collaborating with local partners and maintaining data entry standards. While the KCCSP has overarching structure and programmatic requirements, such as use of specific data collection forms, each KCCSP site worked with state staff on how to best incorporate the KCCSP into their health department and community. Additional site visits were made to the individual KCCSP site locations to evaluate their role in the program, including a random sample audit of records for completeness, and to address any specific questions, needs, or concerns. Support for all KCCSP sites included technical assistance conference calls every month to address concerns from screening sites and inform them of program changes, reinforce information, and offer opportunities for networking and sharing of best-practices.

Colonoscopy quality preparation standards described by the American Society for Gastrointestinal Endoscopy state that the rate of adequate bowel prep (fair to excellent) should be $\geq 85\%$. Table 3 below shows that the KCCSP exceeded that standard in each year of service. Further, the program reduced unreported prep quality by modifying contract language to withhold payment if preparation quality was not included on the colonoscopy procedure report. The cecum was reached on all but two colonoscopies in which the patient had a tortuous colon. There were no reported adverse events.

Table 3: Colonoscopy Preparation Quality by Program Year (Source: KCCSP database)				
Prep Quality	12/13*	13/14	14/15	15/16
Poor	3%	2%	0%	2%
Fair	7%	9%	6%	7%
Good	42%	48%	63%	52%
Excellent	42%	33%	29%	39%
Not Reported	6%	8%	2%	0%

*FY13 services did not begin until January1, 2014, making this a 6 month time period compared to the last 3 years during which services were provided for a full 12 month period.

Review of Colorectal Cancer Cases – Demographics, Pathology, Staging and Survival Status

This section provides more detail on the 13 cancers diagnosed during the active implementation of the KCCSP program. One cancer was diagnosed in the first six months of program operation (January 2013 to June 2014); eight colorectal cancers were diagnosed in the second year between July 2013 and June 2014, and four more colorectal cancers diagnosed in the third year of operation between July 2014 and June 2015. There were no colorectal cancers diagnosed during the final year of program operation spanning July 2015 to June 2016.

Table 4: Summary of Cancers Diagnosed in Kentucky Cancer Screening Program (Source KCCSP database and Kentucky Cancer Registry)				
Program Year (FY)	Number	Race and Gender	Number	
12/13	1	African American	3	
13/14	8	White	9	
14/15	4	Other	1	
15/16	0	Limited Race breakdown pro	ovided due to HIPPA	
Total	13			
		Male	6	
		Female	7	
		Total	13	

Data from the KCCSP was electronically matched to Kentucky Cancer Registry data in order to provide more detailed information on the pathology and staging of the cancers detected among participants. The match was performed on all screening cases in order to identify any cancers found outside of the KCCSP services (Table 5). This match identified four cases of colorectal cancer which had been diagnosed after the person had been screened by KCCSP. Three of those cases had a negative FIT test result in the program, and one had a colonoscopy in which a hyperplastic polyp was removed.

Table 5: Cancers diagnosed outside of KCCSP (Source: KCCSP Database and Kentucky Cancer Registry)					
Program	Number	Race and Gender Number			
Year (FY)					
12/13	0		African American	1	
13/14	2		White	2	
14/15	1		Other	0	
15/16	1				
Total	4		Male	1	
			Female	3	

Table 6 below shows the primary site, pathology and staging of the colorectal cancers diagnosed as part of the KCCSP, as well as the same information for the colorectal cancers diagnosed outside the program. The most common site was the rectum (5); followed by the sigmoid colon (3), descending colon (2), and the ascending colon, cecum, and rectosigmoid junction with one case each. Four additional cancers were diagnosed in people initially screened in the KCCSP program in the time following their participation in the program when they were covered by insurance.

Table 6: Colorectal Cancer Site, Pathology and Stage for those screened by KCCSP (Source: Kentucky Cancer Registry)				
Primary Site	Pathology Code and Description	Stage		
Ascending Colon	8013 – Large cell neuroendocrine carcinoma	UNK		
Cecum	8140 – Adenocarcinoma, NOS	IIA		
Descending Colon	8210 – Adenocarcinoma in adenomatous polyp	I		
Descending Colon	8263 – Adenocarcinoma in tubulovillous adenoma	IIIA		
Rectosigmoid Junction	8140 – Adenocarcinoma, NOS	IIA		
Rectum, NOS	8000 – Neoplasm, malignant	IIA		
Rectum, NOS	8140 – Adenocarcinoma, NOS	I		
Rectum, NOS	8140 – Adenocarcinoma, NOS	III3B		
Rectum, NOS	8140 – Adenocarcinoma, NOS	IIIC		
Rectum, NOS	8140 – Adenocarcinoma, NOS	IIIC		
Sigmoid Colon	8140 – Adenocarcinoma, NOS	IIA		
Sigmoid Colon	8263 – Adenocarcinoma in tubulovillous adenoma	0		
Sigmoid Colon	8480 – Pseudomyxoma peritonei	IIIC		
	Cancers Diagnosed Post Program Participation			
Rectum, NOS	8070 – Squamous cell carcinoma, NOS	I		
Rectum, NOS	8070 – Squamous cell carcinoma, NOS	IIIA		
Transverse Colon	8140 – Adenocarcinoma, NOS	IIIB		
Ascending Colon	8210 – Adenocarcinoma in adenomatous polyp	IIIC		

The lower the number and letter combination, the earlier the stage of the cancer. Those diagnosed at an earlier stage have a greater chance of being cured through treatment. Data from the Kentucky Cancer Registry demonstrate that all people diagnosed in the

program were successfully navigated to clinically appropriate treatment for their type of cancer.

Certainly, the best outcome from the program is in the survival status of those diagnosed with cancer. Of the 13 people diagnosed in the program, 10 have no evidence of disease and two are living with cancer. One person who is deceased, died from a cause not related to their cancer. Of those four persons diagnosed outside of the program, two are living with no evidence of disease, one is living with cancer, and one is deceased with the cause unknown.

Recommendations

Background – changes to eligibility and covered services

The original target population for this program was people who were uninsured, low income, U.S. Citizens or within the country legally, who are legal residents of Kentucky and meet screening guidelines determined by the American Cancer Society. In April 2016, KRS 214.542 was amended to include eligibility for underinsured individuals. This change was introduced largely due to implementation of the Affordable Care Act and expansion of Medicaid eligibility in Kentucky which reduced the number of low income uninsured adults in the state and because there was a growing realization that underinsured individuals were not eligible. In addition, the amended legislation expanded the types of services that could be provided (dependent on available funding) to include "colon cancer treatment and surveillance".

While it was clear that the program did not have adequate funding to cover expensive colon cancer treatments, it seemed possible to expand coverage to include surveillance (also called diagnostic) colonoscopies. While the cost of a screening colonoscopy is covered as a preventive service under the ACA, costs associated with surveillance/diagnostic colonoscopies are not covered. A surveillance/diagnostic colonoscopy is procedurally identical in nature to a screening colonoscopy, yet the reimbursement rate is significantly higher compared to a screening colonoscopy. Individuals who have not yet met the cost of deductibles and out of pocket expenses associated with their insurance plan will be billed for the service. A colonoscopy is considered to be a surveillance/diagnostic procedure when the patient has previously had a polyp(s) removed, even if the polyp(s) was not pre-cancerous or cancerous, or in cases when a patient shows symptoms of colon cancer which can include abdominal pain, blood in stool, constipation or diarrhea which can be indicative of other intestinal disorders. For those who are underinsured, the cost of following their doctor's orders to properly protect their health by having these surveillance/diagnostic procedures can be overwhelming. Changing the eligibility standards in statute was intended to support those who were at lower income levels, not on Medicaid or Medicare, and insured through high deductible plans, making the cost of lifesaving colonoscopies unaffordable.

In response to the changes in the KRS, the KCCSP staff met with the KCCSAC and selected LHD partners to develop new eligibility guidelines in anticipation of program redesign. Due to funding being unavailable on July 2016, program redesign was not implemented.

Further Recommendations

Per KRS 214.544(7), the advisory committee is providing recommendations for future planning and implementation of the Kentucky Colon Cancer Screening Program. These recommendations for the program are to:

- 1. Operationalize a definition of underinsured;
- 2. Continue to focus on public awareness activities which improve CRC screening rates;
- 3. Determine if the Surgery on Sunday program can be expanded to other areas;
- 4. Request that hospitals review their community benefit to include colon cancer screening within the limitations of the IRS guidelines;
- 5. Review grant opportunities for to support increased CRC screening;
- 6. Work with the Kentucky Cancer Foundation for potential support for colon cancer screening;
- 7. Continue to educate decision makers on gaps in funding for CRC screening.

Appendix A: Statutes and Administrative Regulations

I. 214.540 Definitions for KRS 214.540 to 214.544 -- Establishment and limitation of Colon Cancer Screening Program.

- (1) As used in KRS 214.540 to 214.544:
 - (a) "Department" means the Department for Public Health in the Cabinet for Health and Family Services; and
 - (b) "Program" means the Colon Cancer Screening Program.
- (2) The Colon Cancer Screening Program is hereby established for the purposes of:
 - (c) Increasing colon cancer screening;
 - (d) Reducing morbidity and mortality from colon cancer; and
 - (e) Reducing the cost of treating colon cancer among citizens of the Commonwealth.
- (3) The provisions of KRS 214.540 to 214.544 shall be limited to the amount of appropriations to the department for the Colon Cancer Screening Program.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 126, sec. 1, effective July 15, 2008.

II. 214.542 Eligibility for Colon Cancer Screening Program -- Services provided -- Income-based fee schedule -- Funding -- Affordability -- Data collection -- Administrative regulations.

- (1) The program shall provide colon cancer screening for uninsured and underinsured individuals who are eligible based upon the current American Cancer Society Colorectal Cancer Screening Guidelines.
- (2) Services provided under the program may be undertaken by private contract for services or operated by the department. The program may also provide referral, examination, and rescreening services for the benefit of uninsured and underinsured individuals for whom further examination or treatment is indicated by the colon cancer screening. Colon cancer treatment and surveillance may be provided to uninsured and underinsured individuals if program funding is available.
- (3) The department shall adopt a schedule of income-based fees that may be charged for colon cancer screening, examination, surveillance, treatment, and rescreening for uninsured and underinsured individuals. The schedule adopted shall be such that the screening, examination, and rescreening is affordable and accessible to the largest possible number of uninsured and underinsured individuals throughout the Commonwealth.
- (4) The department may accept any grant or award of funds from federal or private sources for carrying out the provisions of this section.

- (5) The department shall establish a data collection system including the number of individuals screened, the demographic characteristics of the individuals screened, and the types of colon cancer screening tests, examinations, surveillance, treatments, and rescreening services performed under the program.
- (6) The department shall promulgate administrative regulations to implement the provisions of this section, including:
- (a) A schedule of income-based fees that may be charged for colon cancer screening, examination, surveillance, treatment, and rescreening as required by subsection (3) of this section; and
- (b) A data collection system as required by subsection (5) of this section.

Effective: April 7, 2016

History: Amended 2016 Ky. Acts ch. 42, sec. 1, effective April 7, 2016. -- Amended 2010 Ky. Acts ch. 168, sec. 1, effective July 15, 2010. -- Created 2008 Ky. Acts ch. 126, sec. 2, effective July 15, 2008.

Legislative Research Commission Note (7/15/2010) 2010 Ky. Acts ch. 168, sec. 3 provides that the addition of subsection (3) of this statute in Section 1 of that Act shall be in memory of Richard "Butch" Stewart.

III. 214.543 Kentucky Colon Cancer Screening Program fund.

- (1) (a) There is hereby created a restricted fund to be known as the Kentucky Colon Cancer Screening Program fund.
 - (b) The fund shall be administered by the Finance and Administration Cabinet.
 - (a) The fund shall include moneys appropriated by the General Assembly for the purpose of the Colon Cancer Screening Program and moneys collected under KRS 214.542.
- (2) Moneys in the fund shall be used by the department to administer KRS 214.540 to 214.544.
- (3) Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the fiscal year shall not lapse but shall be carried forward into the succeeding fiscal year to be used in accordance with subsection (2) of this section.
- (4) Interest earned on any moneys in the fund shall accrue to the fund.
- (5) Moneys in the fund are hereby appropriated for the purposes set forth in KRS 214.540 to 214.544.

Effective: July 15, 2010

History: Created 2010 Ky. Acts ch. 168, sec. 2, effective July 15, 2010.

Legislative Research Commission Note (7/15/2010). 2010 Ky. Acts ch. 168, sec. 3 provides that the creation of this statute in Section 2 of that Act shall be in memory of Richard "Butch" Stewart.

IV. 214.544 Colon Cancer Screening Advisory Committee -- Membership -- Duties -Annual report -- Colon cancer screening, education, and outreach programs.

- (1) A Colon Cancer Screening Advisory Committee shall be established within the Kentucky Cancer Consortium. The advisory committee shall include:
 - (a) One (1) appointee appointed by the Speaker of the House;
 - (b) One (1) appointee appointed by the President of the Senate;
 - (c) The deputy commissioner of the Department for Public Health;
 - (d) Two (2) at-large members appointed by the Governor;
 - (e) The director of health initiatives for the mid-south division of the American Cancer Society;
 - (f) The director of the Kentucky Cancer Program at the University of Kentucky;
 - (g) The director of the Kentucky Cancer Program at the University of Louisville;
 - (h) The director of the Kentucky Cancer Registry;
 - (i) The director of the Colon Cancer Prevention Project;
 - (j) The chair of Kentucky African Americans Against Cancer; and
 - (k) The director of the Kentucky Cancer Consortium.

Members of the advisory committee shall be appointed for a term of four (4) years.

- (2) (a) Members appointed under subsection (1)(a) to (d) of this section shall be appointed as follows:
 - 1. Members shall be appointed for a term of four (4) years, except as provided in subparagraph 2. of this paragraph;
 - 2. The initial appointments shall be for a period of two (2) years; thereafter, the appointments shall be for a term of four (4) years; and
 - 3. Members shall not serve more than two (2) terms of four (4) years.
 - (b) Members serving under subsection (1)(e) to (k) of this section shall serve by virtue of their positions and shall not be subject to term limits.
- (3) The chair of the advisory committee shall be elected from the membership of the advisory committee to serve for a two (2) year term. A member of the advisory committee may designate an alternate to attend meetings in his or her place.
- (4) The advisory committee may add members from other organizations as deemed appropriate.
- (5) The advisory committee shall provide recommendations for the overall implementation and conduct of the Colon Cancer Screening Program.
- (6) The advisory committee shall establish and provide oversight for a colon cancer screening public awareness campaign. The Cabinet for Health and Family Services shall contract with the Kentucky Cancer Consortium at the University of Kentucky to provide the required support. The amount of the contract shall not be included in the base budget of the university as used by the Council on Postsecondary Education in determining the funding formula for the university.
- (7) The Colon Cancer Screening Advisory Committee shall provide an annual report on

implementation and outcomes from the Colon Cancer Screening Program and recommendations to the Legislative Research Commission, the Interim Joint Committee on Health and Welfare, the Interim Joint Committee on Appropriations and Revenue, the Governor, the secretary of the Cabinet for Health and Family Services, and the commissioner of the Department for Public Health.

(8) The Kentucky Cancer Program, jointly administered by the University of Kentucky and the University of Louisville, shall establish a colon cancer screening, education, and outreach program in each of the state area development districts. The colon cancer screening, education, and outreach program shall focus on individuals who lack access to colon cancer screening. The Cabinet for Health and Family Services shall contract with the University of Louisville and the University of Kentucky to provide the required support. The amount of the contract shall not be included in the base budgets of the universities as used by the Council on Postsecondary Education in determining the funding formula for the universities.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 126, sec. 3, effective July 15, 2008.

Legislative Research Commission Note (7/15/2008). There are two incorrect internal references in subsection (2) of this statute that have not been corrected in codification because they are drafting errors, not manifest clerical or typographical errors correctable by the Reviser of Statutes under KRS 7.136(1)(h). However, the reference in subsection (2)(a) to "subsection (1) of this section" should have been drafted as "subsection (1)(a), (c), and (d) of this section" since the deputy commissioner of the Department for Public Health referenced in subsection (1)(c) of this statute serves as an ex officio, not appointed, member of the advisory committee. Likewise, the reference in subsection (2)(b) of this statute to "subsection (1)(e) to (k) of this section" should have been drafted as "subsection (1)(c) and (e) to (k) of this section."

V. 902 KAR 21:020. Kentucky Colon Cancer Screening Program.

RELATES TO: KRS 205.520, 211.090(3), 211.180(1), 214.540-214.544, Chapter 304.17A STATUTORY AUTHORITY: KRS 194A.050(1), 214.542(6)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 214.542(6) requires the cabinet to promulgate administrative regulations to implement the Kentucky Colon Cancer Screening Program. This administrative regulation establishes the eligibility criteria, services, and requirements for participation in the colon cancer screening program.

Section 1. Definitions. (1) "Applicant" means an individual desiring services paid in part by the screening program.

- (2) "Contractor" means a person or facility that agrees to the terms of participation of the screening program in contract and ensures services are delivered pursuant to the screening program terms.
 - (3) "Department" means the Department for Public Health or its designated representative.
- (4) "Screening program" means the Kentucky Colon Cancer Screening Program administered by the department.

- Section 2. Eligibility Criteria. (1) In order to receive a service established in Section 3 of this administrative regulation, an applicant shall:
- (a) Meet the eligibility for screening pursuant to American Cancer Society Colorectal Cancer Screening Guidelines;
 - (b) Be a legal resident of Kentucky;
- (c) Have an individual income at or below 300 percent of the federal poverty level, established annually by the United States Department of Health and Human Services pursuant to 42 U.S.C. 9902(2); and
- (d) If covered by health insurance, have an out-of-pocket maximum that is five (5) percent or more of the individual's annual income.
- (2) A service received without prior authorization from the screening program is not eligible to be covered.
- Section 3. Services. If funding is available, the services to be paid in part by the screening program shall include colon cancer screening tests and may include:
- (1) Referral, examination, and rescreening for individuals for whom further examination or treatment is indicated by the colon cancer screening;
 - (2) Surveillance; and
 - (3) Treatment.

Section 4. Contractor Responsibility. A contractor shall:

- (1) Complete a KCCSP 101 form, Kentucky Colon Cancer Screening Program Eligibility and Enrollment, with the applicant;
- (2) Review the completed KCCSP 102 form, Kentucky Colon Cancer Screening Program Affidavit;
 - (3) Determine applicant eligibility pursuant to Section 2 of this administrative regulation;
 - (4) If the applicant is eligible, provide service or referral for service; and
- (5) Report program data into the data collection system pursuant to Section 6 of this administrative regulation.

Section 5. Data Collection System. The department shall establish a data collection system in accordance with KRS 214.542(5).

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) Form "KCCSP 101, Kentucky Colon Cancer Screening Program Eligibility and Enrollment", 2/2017; and
 - (b) Form "KCCSP 102, Kentucky Colon Cancer Screening Program Affidavit", 2/2017.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, First Floor, Health Services Building, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (43 Ky.R. 1348, 1592, 1767; eff. 5-5-2017.)